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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

ARINDAM BANERJEE, et al. Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

AVINGER, INC., JEFFREY M. SOINSKI, MATTHEW B. FERGUSON, DONALD A. LUCAS, JOHN B. SIMPSON, JAMES B. MCELWEE, JAMES G. CULLEN, THOMAS J. FOGARTY, CANACCORD GENUITY INC., COWEN AND COMPANY, LLC, OPPENHEIMER & CO. INC., BTIG, LLC, and STEPHENS INC.,

Defendants.

Case No.: 17-cv-3400-CW

CLASS ACTION

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiffs Arindam Banerjee and Jogesh Harjai, Court-appointed Lead Plaintiffs, together with the Additional Plaintiffs identified herein (collectively, with Lead Plaintiffs, "Plaintiffs"), by and through their attorneys, allege the following based upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, Plaintiffs' counsel's investigation, which includes, without limitation: (1) review and analysis of regulatory filings made by Avinger, Inc. ("Avinger" or the "Company") with the U.S. Securities and Exchange Commission ("SEC"); (2) review and analysis of analyst reports, press releases, conference call transcripts, and media reports issued by and disseminated by Avinger; (3) information obtained from former employees of the Company; and (4) review of other publicly-available information concerning Avinger.

SUMMARY OF THE ACTION

1. This is a class action on behalf of all persons and entities that purchased or otherwise acquired shares of Avinger common stock pursuant and/or traceable to the Company's materially false, misleading and incomplete Registration Statement and accompanying Prospectus incorporated therein (collectively, the "Offering Documents" or "IPO Registration Statement") issued in connection with Avinger's January 30, 2015, initial public offering ("IPO" or "Offering"), as well as all persons and/or entities who purchased or acquired the Company's common stock between January 30, 2015 and April 10, 2017, inclusive (the "Class Period"). Plaintiffs pursue remedies pursuant to the Securities Act of 1933 ("Securities Act"), the Securities Exchange Act of 1934 ("Securities Exchange Act"), and SEC Rule 10b-5 promulgated thereunder.

2. Avinger is purportedly a commercial-stage medical device company that designs, manufactures, and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease or "PAD." The Offering Documents stated that Avinger's mission was to improve the treatment of vascular disease through the introduction of products based on its "lumivascular platform," which the Offering Documents described as "the only technology that offers real-time visualization of the inside of the artery during PAD treatment." The Offering Documents further stated that the Company believed that the approach offered by its technology "will significantly improve patient outcomes by providing physicians with a clearer

picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between [arterial] plaque and healthy arterial structures," and thereby avoiding or significantly reducing the kinds of arterial damage or other complications (such as restenosis) associated with other forms PAD treatment. The Offering Documents noted that Avinger's "current suite" of commercially available lumivascular products included its "Lightbox imaging console" and its "Ocelot family of catheters," which were designed to allow physicians to penetrate (cut through) a total blockage in an artery (known as a chronic total occlusion, or "CTO").[1]

3. However, as part of Avinger's stated mission to "dramatically improve" the treatment of vascular disease through the introduction of products based on its "lumivascular platform," the Offering Documents placed particular stress on the critical importance of Avinger's new Pantheris device, which was described as an "image-guided atherectomy[2] device, designed to allow physicians to remove arterial plaque in PAD patients with precision." As the Offering Documents further stated, Pantheris was in the middle of a clinical trial in the U.S. (the "VISION" trial), which was intended to support an application to the U.S. Food and Drug Administration ("FDA") for 510(k) clearance (to permit commercial sales of the device) in the second half of 2015. As of the date of the IPO, 116 patients at 19 separate sites (out of a total planned enrollment of roughly 133 patients) had already been enrolled in the VISION trial. Avinger touted Pantheris in the prospectus, describing it as the "first atherectomy catheter to incorporate real time OCT [optical coherence tomography] intravascular imaging," and stating that "[w]e believe that Pantheris will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures."

[1] The Offering Documents also noted that Avinger's *non*-image based "Wildcat" and "Kittycat2" catheter products were still commercially available, but that its sales of those products "have declined and continue to decline as we focus on the promotion of our lumivascular platform products." Indeed, the Offering Documents further stated that Avinger had significantly reduced the number of its employees in the last 18 months, from 168 to 115, "to better align resource utilization with our corporate strategy as we transitioned our focus from non-imaging products to lumivascular platform products, including Pantheris [*see* below]."

[2] An "atherectomy" is a procedure that utilizes a catheter with a sharp blade on the end to remove plaque from a blood vessel. The catheter is inserted into the artery through a small puncture in the artery.

4. In the IPO, Avinger sold five million shares at a public offering price of $13.00 per share. The Company received net proceeds of approximately $56.9 million from the IPO.

5. However, unbeknownst to investors, as of the date of the IPO and during the Class Period, Avinger's all-important Pantheris product suffered from significant product defect and reliability issues. As a result, the Offering Documents and Defendants' statements during the Class Period were materially false and misleading and/or omitted to state: (1) that the Company's Pantheris product had substantial reliability issues; (2) that the reliability issues would likely have a negative impact on Pantheris sales and jeopardize Avinger's ability to successfully launch the product on a commercial basis; and (3) that, as a result of the foregoing, the statements in the Offering Documents regarding Avinger's business, operations and prospects were materially false, misleading and/or incomplete, and/or lacked a reasonable basis.

6. For example, as various former Avinger employees identified herein as Confidential Witnesses ("CWs") confirmed, prior to and as of the IPO – as well as during the Class Period – Pantheris was suffering from significant problems with the fiber-optic cables, and resulting imaging problems. In particular, as Avinger engineering personnel had concluded, Avinger's testing of the Pantheris device failed to adequately simulate real-world use, specifically in connection with tortuosity (involving the ability of the product to make multiple turns as it navigates through the vasculature), and the Company's engineers therefore repeatedly asked Avinger's Chief Technology Officer, including prior to the IPO, that the Company to take steps to significantly improve the quality, reliability and durability of the fiber optic cable used in the Pantheris. However, these requests were repeatedly rebuffed.

7. The significant and undisclosed problems with Avinger's Pantheris product would ultimately come back to haunt the Company – and torpedo the value of class members' investments in its shares. For example, on July 12, 2016, the Company announced disappointing preliminary second quarter 2016 results, which it attributed in part to "lower than expected" utilization of Pantheris in the second quarter. Avinger also reported that customer complaints forced the Company to try to implement corrective changes to the Pantheris, including with respect to improving its fiber optic imaging cables and robustness. Analysts also reacted

negatively to these disclosures, with one describing the commentary about the product quality problems "alarming." On July 13, 2016 Avinger's stock price fell $4.54 (or 39.7%), from $11.43 to only $6.89 per share, on unusually heavy trading volume. As Pantheris continued to be plagued by product problems and related product returns, customer complaints and dismal sales – and with the Company also later admitting that it needed to significantly toughen its product testing and validation protocols if it wanted to avoid a similarly disastrous commercial launch for future generations of Pantheris product – Avinger's stock has only continued to decline. Indeed, as recently November 17, 2017, the price of Avinger's common stock traded as low as $0.23 per share – reflecting a staggering a decline of $12.77, ***or a more than a 98% decline,*** from its IPO price of $13.00 per share. Plaintiffs now bring this action, on behalf of themselves and the Class that they seek to represent, to recover damages for the staggering losses that they have suffered in connection their purchases of Avinger shares.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§77k and 77o), Sections 10(b) and 20(a) of the Securities Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5). This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act (15 U.S.C. § 77v) and pursuant to 28 U.S.C. §1331 and §27 of the Securities Exchange Act.

9. Venue is also proper in this district under Section 22 of the Securities Act, 15 U.S.C. § 77v, which provides that any suit under the Act may be brought "in the district wherein the defendant is found or is an inhabitant or transacts business." Venue is further appropriate in this district pursuant to §27 of the Securities Exchange Act and 28 U.S.C. §1391(b). Many of the violations of law complained of herein occurred in this district, including the dissemination of the materially false and misleading statements complained of herein. In addition, Avinger's principal executive offices are located in this district. Each of the other Defendants also has sufficient contacts with this district, or otherwise purposefully availed himself or itself of benefits of this

district, so as to render the exercise of jurisdiction over each by this district consistent with traditional notions of fair play and substantial justice.

PARTIES

10. Lead Plaintiffs Arindam Banerjee and Jogesh Harjai purchased shares of Avinger common stock during the Class Period and pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and have been damaged thereby.

11. Plaintiffs Lindsay Grotewiel and Todd Vogel (the "Additional Plaintiffs") purchased shares of Avinger common stock during the Class Period and pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and have been damaged thereby.

12. Defendant Avinger, Inc. is incorporated in Delaware and its principal executive offices are located at 400 Chesapeake Drive Redwood City, California 94063. Its common stock trades on the NASDAQ Stock Market (the "NASDAQ") under the symbol "AVGR."

13. Defendant Jeffrey M. Soinski ("Soinski"), at all relevant times, was the Chief Executive Officer ("CEO") and a Director of Avinger, and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

14. Defendant Matthew B. Ferguson ("Ferguson"), at all relevant times, was the Chief Financial Officer ("CFO") and Chief Business Officer ("CBO") of Avinger, and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

15. Defendant John B. Simpson ("Simpson"), at all relevant times, was the Executive Chairman of the Board of Directors of Avinger, and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

16. Defendant Donald A. Lucas ("Lucas"), at all relevant times, was a Director of Avinger and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

17. Defendant James B. McElwee ("McElwee"), at all relevant times, was a Director of Avinger and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

18. Defendant James G. Cullen ("Cullen"), at all relevant times, was a Director of Avinger, and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

19. Defendant Thomas J. Fogarty ("Fogarty"), at all relevant times, was a Director of Avinger and signed or authorized the signing of the Company's IPO Registration Statement filed with the SEC.

20. Defendants Soinski, Ferguson, Lucas, Simpson, McElwee, Cullen, and Fogarty are collectively referred to hereinafter as the "Individual Defendants."

21. Defendant Canaccord Genuity Inc. ("Canaccord") served as an underwriter for Avinger's IPO. In the IPO, Canaccord agreed to purchase 1,750,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

22. Defendant Cowen and Company, LLC ("Cowen") served as an underwriter for the IPO. In the IPO, Cowen agreed to purchase 1,750,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

23. Defendant Oppenheimer & Co. Inc. ("Oppenheimer") served as an underwriter for the IPO. In the IPO, Oppenheimer agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

24. Defendant BTIG, LLC ("BTIG") served as an underwriter for the IPO. In the IPO, BTIG agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

25. Defendant Stephens Inc. ("Stephens") served as an underwriter for the IPO. In the IPO, Stephens agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

26. Defendants Canaccord, Cowen, Oppenheimer, BTIG and Stephens are collectively referred to hereinafter as the "Underwriter Defendants." The Underwriter Defendants received lucrative fees and commissions, totaling in excess of $4.5 million, for their role in the IPO.

27. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of the Company, were privy to confidential and proprietary information

concerning the Company, its operations, finances, financial condition, and present and future business prospects. Additionally, as set forth more fully below, the Individual Defendants had access to material adverse non-public information concerning the Company. Because of their positions within the Company, the Individual Defendants had access to non-public information about the Company's business, finances, products, markets, and present and future business prospects via internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew, or were deliberately reckless in not knowing, that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

28. The Individual Defendants are liable as direct participants in the wrongs alleged herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 15 of the Securities Act and Section 20(a) of the Securities Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct alleged. Because of their positions of control, the Individual Defendants were able to, and did, directly or indirectly, control the conduct of the Company's business.

29. The Individual Defendants, because of their positions within the Company, controlled and/or possessed the authority to control the contents of the Company's reports, press releases, and presentations to securities analysts and, through them, to the investing public. The Individual Defendants were provided with copies of the Company's statements alleged to be misleading herein, prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

30. The Individual Defendants, as senior executive officers and/or directors – and as controlling persons of a publicly traded company whose common stock was, and is, governed by the federal securities law – had a duty to promptly disseminate accurate and truthful information

with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

31. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud and/or deceit on purchasers of the Company's common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. This scheme: (1) deceived the investing public regarding the Company's business, operations and management, and the intrinsic value of the Company's common stock; (2) enabled the Company to obtain additional capital at favorable prices, create a public market for its common stock, and gain access to the public equity markets; and (3) caused Plaintiffs and members of the Class to purchase the Company's common stock at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

A. The Company's False and/or Misleading Offering Documents

32. On January 29, 2015, Avinger filed an amendment to the Form S-1 registration statement originally filed on December 30, 2014. The amendment, which included the text of the IPO Prospectus dated January 29, 2015, forms part of the IPO Registration Statement.

33. In the Prospectus, the Company emphasized the critical importance of its Pantheris product, and how its unique real-time imaging capabilities provided the basis for a dramatic improvement in vascular disease by allowing physicians to remove only harmful arterial plaque while avoiding healthy arterial tissue. For example, the Prospectus stated:

> ***We are … developing Pantheris, our image-guided atherectomy device, designed to allow physicians to remove arterial plaque in PAD patients with precision.*** Pantheris is currently undergoing a U.S. clinical trial intended to support a 510(k) submission in the second half of 2015 to the U.S. Food and Drug Administration, or FDA. We believe that Pantheris, if cleared by FDA, will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments include stents, angioplasty, and atherectomy devices, which are catheter-based products for the removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which we refer to as the black line.

Our lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding healthy portions of the artery.

During the third quarter of 2014, we began enrolling, and we are continuing to enroll, patients in VISION, a clinical trial designed to support a filing with FDA for our Pantheris atherectomy device. VISION is designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging. Data collection from the VISION trial is ongoing and data monitoring and auditing of the acute procedural data and 30-day follow-up data is currently underway. As of January 12, 2015, preliminary acute procedural data were available for 116 patients, and 30-day follow-up data were available for 35 of these patients, and results reviewed by an independent core lab are available for 113 lesions.

* * *

Our Solution

We believe the combination of enhanced visualization and the ability to precisely target the diseased portion of an artery will allow physicians to access difficult to treat areas and significantly improve the safety and efficacy of endovascular procedures for patients. We believe that our lumivascular platform provides the following benefits to physicians, hospitals and patients:

• Improved efficacy through reduced risk of restenosis. Our lumivascular platform is designed to provide physicians with a clear picture from inside the artery during treatment. This visualization helps physicians to avoid disrupting the black line during an intervention, which we believe reduces the risk of restenosis.

• Safety of endovascular procedures. Serious adverse events such as perforations and dissections may be reduced during endovascular procedures using our lumivascular platform.

• Expanded patient population eligible for endovascular treatment of PAD. Our lumivascular platform is designed to allow physicians to treat complex PAD cases due to our increased CTO crossing success rates. Due to improved safety of our lumivascular platform products, we believe physicians will be more likely to use our products to treat patients who would otherwise be medically managed.

* * *

> Our pioneering lumivascular platform combines best-in-class interventional devices with optical coherence tomography, or OCT, a high resolution, lightbased, radiation-free intravascular imaging technology. ***Our lumivascular platform currently provides physicians with real-time OCT images from the inside of an artery during CTO crossing, and we believe Pantheris will be the first product to offer intravascular visualization during atherectomy***.
>
> * * *
>
> *Improved efficacy through reduced risk of restenosis*. Clinical evidence supports the proposition that more desirable outcomes in treating PAD are achieved by minimizing black line disruption, thereby reducing the risk of restenosis. Our lumivascular platform is designed to provide physicians with a clear picture from inside the artery during treatment. This visualization helps physicians to avoid disrupting the black line during an intervention, which we believe reduces the risk of restenosis. In addition, the directional nature of our catheters is designed to enable physicians to accurately target the diseased area, resulting in less damage to arterial structures and allowing for the precise removal of plaque. . . .

34. On January 30, 2015, the Company filed with the SEC the Prospectus, which was incorporated by reference into the Registration Statement that was declared effective on January 29, 2015. The Prospectus reaffirmed the statements identified above.

B. <u>Avinger's Subsequent Materially False, Misleading, or Incomplete Statements</u>

35. After the IPO, Avinger and the Individual Defendants continued to tout the prospects of Avinger's Pantheris product.

36. On May 6, 2015, Avinger announced its financial results for the first quarter of 2015, and that it had achieved the "primary efficacy endpoint" for its VISION study. The release also quoted Defendant Soinski as stating "[W]e remain on track for the anticipated commercial launch of Pantheris in early 2016," and quoted Defendant Simpson as stating "I am delighted with the very positive results we are already seeing out of our VISION trial . . . and I am very pleased by the progress of Pantheris."

37. On July 28, 2015, Avinger announced its financial results for the second quarter of 2015, and emphasized that it had "[s]urpassed" the "primary efficacy endpoint performance goal in 30-day data from [the] VISION [study]." The release also quoted Defendant Soinski as stating:

> I am pleased with the progress we've made in the first half of 2015 on the objectives we set for the year. We are on track to complete six-month follow-up data analysis in our VISION Trial to support a 510(k) submission for Pantheris in the second half of this year. We have also made meaningful progress towards

> building the infrastructure to support a broad-scale commercial launch of Pantheris in the first half of 2016[.]

38. The release also quoted Defendant Simpson as stating:

> I have to say that these are genuinely exciting times to be at Avinger and witness and participate in the progress made toward the completion of the VISION Trial. . . . I am equally pleased with the early, very positive feedback we are hearing from physicians who have used the Pantheris device to treat the PAD patients in the VISION trial.

39. On November 5, 2015, Avinger announced its financial results for the third quarter of 2015, and stated that it had "[r]eceived 510(k) clearance from the [FDA] to commence U.S. commercialization of Pantheris[.]" The release also stated that the Company and its Pantheris product had "[s]uccessfully completed [the] VISION trial, achieving all primary and secondary safety and effectiveness endpoints." The release also quoted Defendant Soinski as stating: "Our momentum continued to build through the third quarter, with the achievement of several strategic milestones, including exceptional six-month data from our VISION trial and 510(k) clearance from the FDA to begin commercializing Pantheris in the U.S." The release also quoted Defendant Simpson as stating: "We are on the threshold of launching Pantheris, and I remain as confident as ever in our ability to dramatically change the treatment of vascular disease."

40. On March 1, 2016, Avinger announced its financial results for the fourth quarter and full year 2015, which stated that it had "[c]ommenced commercialization of an enhanced version of the Pantheris . . . following receipt of a 510(k) clearance from the [FDA] on March 1, 2016." The release also quoted Defendant Soinski as stating: "As we enter 2016, I am confident that we are well positioned for growth, driven by the commercial launch of Pantheris and continued expansion of our installed base of lumivascular accounts." The release also quoted Defendant Simpson as stating: "I am exceptionally pleased with the results and feedback from the initial users of Pantheris."

41. On May 4, 2016, Avinger announced its financial results for the first quarter of 2015, which stated that it "began commercialization of an enhanced version of the Pantheris . . . on March 1, 2016," and that it had "[r]eceived initial Pantheris orders from 60% of [existing Avinger] lumivascular accounts." The release also quoted Defendant Soinski as stating: "We are

pleased with the early adoption of Pantheris and the early physician interest in the product[.] . . . The launch of the Pantheris is a significant milestone which we expect to drive strong top-line growth in 2016."

C. Reasons Why Avinger's Offering Documents and Subsequent Statements Were False, Misleading and/or Materially Incomplete

42. The IPO Registration Statement contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and were not prepared in accordance with the rules and regulations governing their preparation. Under applicable SEC rules and regulations, including Item 303 of SEC Regulation S-K, the IPO Registration Statement was required to disclose known trends, events or uncertainties that were having, and were reasonably likely to have, an impact on the Company's continuing operations.

43. The IPO Registration Statement was materially inaccurate, incomplete and misleading, and/or omitted to include material information required to be stated therein, because it failed to disclose that: (1) that the Company's Pantheris product had substantial reliability issues; (2) that the reliability issues would negatively impact the Company's sales; (3) that the Company's products were not commercially viable; and (4) that, as a result of the foregoing, Defendants' statements in the IPO Registration Statement regarding Avinger's products, business and prospects, were materially false, misleading, incomplete and/or lacked a reasonable basis.

44. The CW accounts demonstrate the materially false, incomplete and/or misleading nature of the statements contained in the Offering Documents and the subsequent Avinger press releases referenced in §B above. Indeed, because the Offering Documents failed to disclose at the time of the IPO that the product on which Avinger's future success depended, Pantheris, was plagued by significant fiber optic cable defects and resulting imaging problems. These problems were so severe that, both before the IPO (as well as after) the Company's engineers repeatedly asked the Company's Chief Technology Officer to take steps to improve the quality of the fiber optic cable's being used in the product, only to have their requests repeatedly rebuffed. Similarly, the SEC filings referenced in §B above were materially false, incomplete, and/or misleading when

made for failing to disclose that Pantheris was plagued by significant fiber optic cable defects and resulting imaging problems.

45. For example, according to CW1, who (after a previous stint at Avinger) worked as an R&D Engineer at the Company's Redwood, CA headquarter from late 2014 until April 2017 (where CW1 reported to Director of R&D Rick Newhauser ("Newhauser") and interacted daily with Chief Technology Officer ("CTO") Himanshu Patel ("Patel")), CW1 worked primarily on the Pantheris device. In this role, CW1 was responsible for the mechanical design and testing of certain components of the Pantheris device – primarily the braided driveshaft and torqueshaft components – and was also heavily involved in verification and validation ("V&V") testing, using both benchtop and animal-model testing processes. CW1 was responsible for designing the V&V testing specifications, including drafting test protocols, running the tests themselves, and training technicians to perform the tests. The V&V testing process tested for different measurable outcomes – including the reliability and/or durability of the Pantheris device – to ultimately ensure that the device's design met all specifications and was ready to be launched commercially.

46. As CW1 described, Avinger's benchtop testing on the design of the Pantheris device was "verified" by running a series of tests on the device as it rested on a benchtop, which would then be followed by a "validation" process based on animal-model testing which was purportedly meant to evaluate performance under more "real-world" conditions. For the validation process, Avinger used a pig's aorta as a proxy to simulate the environment in which the product would be used in a human. Validation testing sought to confirm the testing results from the verification process.

47. V&V testing outcomes fell into one of three categories: (1) pass; (2) fail; or (3) pass with justification. The "pass with justification" category was one where the device had actually failed the V&V test, but was issued a passing grade due to a purportedly allowable justification. As CW1 stated, the "pass with justification" category raised issues in terms of whether a purported justification was truly acceptable or was simply being used as a method for Avinger to conceal and/or ignore problems to cut costs and/or keep the product's deployment moving forward on schedule.

48. According to CW1, the V&V testing specifications for Pantheris were unrealistic in that they did not adequately simulate what the use of the device would be in the field. Specifically, CW1 stated that the testing of the device was not as rigorous as CW1 and other engineers believed was necessary. One recurring area that CW1 and his colleagues strongly believed needed to be improved was in the area of testing the Pantheris' tortuosity performance. As CW1 explained, the Pantheris device was intended to be able to maneuver through multiple twists and turns within the human body's vasculature as it made its way to the problem area that required the atherectomy. However, Avinger's V&V testing specifications only allowed for at most one turn, and sometimes no turns at all, for the device to handle properly. This lack of tortuosity in the test environment significantly increased the likelihood that a device would nominally be able to pass test specifications – which CW1 characterized as too easy – even though it would be unable to satisfactorily perform in real-world conditions. In particular, as CW1 stated, in the real world maneuvering a Pantheris through the twists and turns of the vascular was a primary factor that could, and did, damage the fiber optic cable within the device, which in turn would compromise the device's image quality. And as CW1 confirmed, one of the most significant risks associated with image quality deterioration was the risk that a physician, who could not properly view the artery and blockage, would remove or damage healthy tissue portions of a patient's artery, instead of (or in addition to) arterial plaque.

49. Avinger's V&V testing for the Pantheris device's reliability and durability involved running the device for a certain amount of time in order to measure the device's performance. As CW1 stated, image failure in the reliability and durability segment of Avinger's V&V testing was "one of the biggest issues that we had," and many of the image failures related to ongoing problems with the Pantheris' fiber optic cables. ***As CW1 put it, "the level of robustness wasn't there, even pre-IPO."***

50. However, rather than confront these problems directly, CW1 stated that the response that Avinger adopted in response to these failures – as dictated by CTO Patel – was to "dial back the [testing] requirements", and to instead rely on "justification[s] from clinical data [from the VISION trial]." In other words, the concept was for Avinger to identify product failures

from the VISION trial, and then extrapolate those from those observed failures to estimate how long the device could run in a given configuration. As a result, Avinger glossed over and discounted Pantheris' failures on the reliability and durability tests that the Company's engineers actually ran by instead giving the device "pass with justification" grades – even though Avinger's reliance on "clinical data" from the VISION trial for this purpose was inappropriate. In particular, the VISION trial was ***not*** designed to measure the Pantheris device's reliability or durability, but was instead only to test its efficacy in treating PAD on a primary patient pool of 133 patients spread out over 19 locations. Accordingly, as CW1 stated, relying on such clinical data was "a hokie justification" for converting Avinger's "fail" grades, based on its own testing, into "pass with justification" grades. CW1 stated that CTO Patel was primarily responsible for approving and directing all test specifications for Pantheris, and for allowing relevant V&V test results to be re-characterized from "fail" to "pass with justification."

51. CW1 also described how Avinger's Senior Vice President of Operations and Quality Assurance, Bunty Banerjee, "would butt heads constantly" with regard to these quality issues. As CW1 recalled, Bannerjee regularly sought higher quality standards and results; by contrast, CTO Patel's priority was to "prove a concept, stick with that design, not worry about improving anything, and then push that [product] out the door." CW1 was aware of the ongoing dynamic between CTO Patel and Banerjee through regular meetings that CW1 attended during CW1's tenure that were held between members of Avinger's R&D and Quality departments to discuss quality and performance issues. In sum, CW1 stated that throughout his tenure, Avinger's product and quality control engineers made repeated requests to Avinger's senior management – including CTO Patel – to improve the Pantheris' fiber-optic cable durability, both during the R&D phase and continuing even after the product was approved and commercially launched. However, Avinger's senior management regularly rebuffed these requests. As a result, it was only after the IPO and Pantheris's commercial launch when, in the face of increasing levels of complaints by physicians who had begun using the product in "real-world" conditions outside of the limitations of a 133-patient study, that CTO Patel and other senior Avinger management began to focus on trying to remedy the device's fiber optic cable/imaging problems. CW1 was also emphatic that,

based on his review of so-called "Wofoo" reports that were prepared in connection with post-commercialization Pantheris product returns by physicians/customers, the most common failure mode category identified in the reports related to imaging issues – and that these imaging issues largely arose from damage sustained to the fiber optic cable.

52. Similarly, CW2 also confirmed that problems with the Pantheris' fiber optic cables were widely known within the Company's headquarters prior to the IPO. CW2 worked at Avinger from the fall of 2011 to August 2016, serving initially as a Product Manager and then as Director of Commercial Operations beginning in October 2014. CW2 reported to VP of Marketing and Business Operations Phil Preuss ("Preuss"), who reported to CFO and Chief Business Officer Ferguson.

53. By virtue of CW2's role, which included efforts to assess and forecast product return rates, CW2 was concerned with the downstream impacts of the imaging problems with Pantheris. CW2 also assisted to a lesser extent with devising product training for customers to try to reduce the risk of breakage as a result of misuse. CW2 also worked on evaluating and revising sales contract terms, specifically in connection with the product warranty coverage and the recourse that customers had as a result of ongoing imaging problems. CW2 was also involved in efforts to forecast return rates, based on his review of prior product returns and customer complaint rates. Based on CW2's work CW2 believed that roughly one-third of all returns and complaints related to imaging problems arising from fiber optic cable quality issues, and stated that another significant issue that gave rise to complaints and returns was the failure of a device's balloons to inflate properly (a malfunction that prevented the device from being able to cut out arterial plaque).[3]

54. CW2 also confirmed that the R&D testing for the Pantheris device was flawed and failed to adequately account for "real world" conditions. As CW2 explained, Avinger's testing

[3] As the Prospectus noted, during an atherectomy procedure with the Pantheris, the balloon beneath the cutting device on the Pantheris is meant to be inflated to move the catheter closer to the plaque, so that the physician can stabilize the device and adjust the cut depth into the plaque as necessary.

utilized a bovine animal model but the consistency of the animal tissue used was materially different from that of human arteries. In particular, the animal tissue that Avinger used for modeling had a smooth consistency which made it relatively easy to cut; by contrast, human arteries have a much rougher consistency which makes them much more difficult to cut. For example, calcium deposits, thrombin levels (which cause blood coagulation and potentially blood clots) and other variables created to a rougher "mixed environment" in real world procedures in humans. In turn, the rougher and more mixed consistencies found in the human vasculature cause variable shearing and feedback forces (and ultimately resistance) on the Pantheris's cutting and fiber optic cables. The combination of the resulting "mixed variable load on the [Pantheris device]" and the fact that the device "was spinning at a relatively high rate of speed, and generating a tremendous amount of torque" also "caus[ed] a lot of the failures" when Pantheris was used in real-world conditions. As such, as CW2 stated, the device required a much more robust design to handle that variable load – which presented a fundamental engineering challenge for Avinger given that the device was so small, with only "millimeters of space" to work with.

55. CW2 was also involved in assessing the extent of the medical community's willingness to adopt Pantheris given the device's ongoing cable, imaging, cutting and balloon problems and related reliability and durability issues. CW2's review indicated that on the one hand physicians appeared to be excited about the Pantheris' new imaging functionality, but on the other hand there was growing frustration because it was this very functionality that was compromised due to ongoing quality issues. Determining whether and to what extent physicians were willing to put up with the hassle of returning defective devices was clearly a concern at Avinger; as CW2 stated, "it was definitely something we were trying to figure out and accurately predict."

56. CW2 also confirmed that the Pantheris' defective cable and image quality problems did not merely raise concerns about irritating physicians, but also raised the issue of imaging problems causing a physician to remove a patient's healthy artery tissue as opposed to, or along with, the intended plague. Moreover, as CW2 also noted, because Pantheris was touted as the first device to provide intravascular visualization during an atherectomy, a defective Pantheris device

could be viewed as simply reverting in functionality to the existing standard of care or status quo – that is, performing atherectomies without viewing or imaging capabilities. Such considerations also factored into Avinger's concerns about customers ultimately invoking their product warranties and related costs and returning products, as well as lackluster sales.

57. Similarly, CW3, who worked as an engineer at Avinger's Redwood City headquarters from the summer of 2011 to the spring of 2017, as a Senior Manufacturing Engineer (through mid-summer 2014), Principal Manufacturing Engineer (through mid-2016) and finally as Principal Quality Engineer (through the spring of 2017), further confirmed that Pantheris continually suffered from ongoing manufacturing and quality problems relating to imaging issues due primarily to broken or damaged optical fiber. As Principal Manufacturing Engineer, CW3 was chiefly responsible for the Pantheris device, which included working with the R&D department during the development phase of Pantheris production and then overseeing commercial production beginning in 2015.

58. As CW3 recalled, CW3 first became aware of the recurring optical cable problems with Pantheris while it was in the R&D phase, and prior to the IPO. As CW3 stated, CW3 acquired this knowledge through regular conversations with personnel at Avinger's headquarters. Indeed, as CW3 stated, in the context of CW3's day-to-day work and throughout CW3's tenure at Avinger "you would always hear about imaging issues," and the problems with imaging of the device were significant. CW3 attributed the ongoing image quality issues to the fact that, when utilized in the field, the Pantheris device was subject to rigorous handling by the operator and/or physician. CW3 also stated that the testing of Pantheris at Avinger headquarters in the laboratory context may not have adequately simulated the actual usage by physicians. Another recurring problem that CW3 identified through reviewing multiple complaints over time was that balloons within the device often did not properly inflate, if at all.

59. These CW accounts all confirm that the representations contained in the IPO Registration Statement – as well as the Company's subsequent statements during the Class Period as alleged herein – were materially false, incomplete and misleading, and failed to disclose material adverse information required to be disclosed therein. Specifically, the accounts of the

CWs demonstrate that: (1) before the Company's IPO, and after, the Company's management was aware of significant problems with the fiber-optic cables and resulting problems with imaging issues; (2) R&D testing of the Company's Pantheris device did not adequately simulate real-world use, specifically in connection with tortuosity, a known contributing factor to fiber-optic cable damage; (3) R&D testing of the device's durability was issued a "pass with justification" grade by relying on unsuitable clinical data, thereby allowing the Company to move forward despite the fact that the test actually yielded a "fail" grade; (4) image quality deterioration issues were tracked and featured prominently in FMEA reports – reports to which the Company's management had access and/or reviewed before the Company's IPO; and (5) R&D Engineers made repeated requests before the Company's IPO to the Company's Chief Technology Officer to improve the fiber optic cable durability, but these requests were repeatedly rebuffed.

D. Post-IPO Disclosures

60. On July 12, 2016, the Company issued a press release that pre-announced disappointing preliminary second quarter 2016 results. The Company attributed its results, in part, to "lower than expected" utilization of Pantheris in the second quarter. As a result, the Company lowered its full year revenue guidance from a range of $25 million to $30 million to a range of $19 million to $23 million. As the Company's July 12 press release further stated.

> Dr. John B. Simpson, Avinger's Founder and Executive Chairman, stated, "Based on our early commercial experience, we have continued to make improvements to Pantheris, and in particular the robustness of its optical imaging fiber, and have received positive feedback from physicians on the performance of the current device.
>
> * * *
>
> The company now expects 2016 revenue to be in the range of $19 million to $23 million, representing year-over-year growth ranging from 78% to 115%, compared to previous guidance for revenue in the range of $25 million to $30 million.

61. After the close of the market on July 12, 2016, the Company held an earnings call to discuss its preliminary results for the second quarter of 2016. On that call, Defendant Soinski stated in part as follows:

> We remain encouraged by the continued growth of our installed base to 126 accounts, an increase of 19 accounts during the second quarter which is the second largest quarterly increase we've achieved in our history.

> However, utilization of disposables has been lower than we had expected. We believe we've identified three main reasons that initial Pantheris utilization has been slower than anticipated and we're taking a series of actions to improve our performance. First, we're still helping physicians understand how Pantheris can best fit into their PAD treatment paradigm both near-term in their current treatment algorithms and longer term as they gain familiarity and use Pantheris in increasingly complex cases.
>
> Second, we experienced some issues with device robustness as we mentioned on our last earnings call and in our Form 10-Q filed on May 9, 2016. We've made changes to the catheter and now believe that the most significant of these issues are behind us.
>
> * * *
>
> The third item we've identified is a slower than anticipated ramp up in sales force productivity. . . .
>
> * * *
>
> While sales this quarter didn't hit our internal expectations, we believe that we've identified the root causes of the slower ramp and that our long-term opportunity remains exciting.

In addition, Defendant Simpson commented:

> This quarter has been a valuable one for us as we've now observed Pantheris usage in a large number of operators in a wide range of lesions. We've also gained important physician feedback which we have used to implement some changes in the product and our sales' force's position in Pantheris. As I mentioned on the last call, while we have had some outstanding early-case experience [unintelligible] has been really remarkable. We have had some initial issues with device robustness, primarily imaging fiber robustness, which are not unusual for a groundbreaking new technology, certainly provided some challenges for our sales team.
>
> I'm pleased to report that based on improvements we made to this device, and in particular to the robustness of the optical imaging fiber, physicians are relaying positive feedback on the improved product. And we now feel the Pantheris performance levels are within the normal range for a new and relatively complex product in our space.

Later in the call, Defendant Soinski referenced Defendant Simpson's earlier comments, when he noted that "as Dr. Simpson talked about, [we] have made some improvements to our number one product issue that we had early in the [Pantheris] launch."

62. In response to a later analyst question on the call regarding "device robustness issues" and issues with the imaging, and whether such issues were "fully behind you now," Defendant Simpson further stated as follows:

> [S] as it relates to the imaging fiber we have [unintelligible] almost like we have put a strain relief and with the fiber. Because in very robust settings if you pull too hard over to cut or to open it, the fiber could crack and when the fiber cracks[s] the images would degrade. So that was – it was never even once a safety issue but it was a huge pain issue and you had to exchange devices and was kind of an annoyance.
>
> I don't think we have to retrain around that because you lose the image so you have to exchange devices to put it into the device. And then the new strain relief seems to have eliminated that almost entire great majority of it. These fibers are fragile, they're tiny, they have enormous benefit but they are fragile and they have to be kind of used, historically they had to be used very careful. Now, with the new devices, you can be much less careful with them and they can still maintain their images and that's really the key element.
>
> So, the fiber not only has it been say protected a little bit but also physicians are a little bit more cautious about how to use it. I don't think this had really affected the learning curve so much as it's been a little bit annoying. I don't know that it's actually affected the ramp. If somebody has a fiber failure, they just put in a new device and they keep going. So I don't know if that answers your question or not.

63. Thereafter, Defendant Simpson engaged in a further colloquy with another analyst regarding robustness issues and whether there were other product quality or design issues that had adversely impacted the Pantheris:

> **Analyst question**: ***I just wanted to start with the robustness issues that you called out; were there any other issues outside of the fiber optic cable crack issues?***
>
> **Defendant Simpson**:
>
> ***Yes.*** So I would say not a real genuine substance. ***The [unintelligible] were also fragile I would say and occasionally we have some balloon leaks*** and again nothing of safety concerns. ***But I think [unintelligible] that most annoying in which I think also the physicians that were using the device felt annoying is that you got all the trouble to get the device all set up on the console and everything done, you put the device in and you get down to the narrow end and then, you'll lose the light***, and there was – and so, we have to really, really [unintelligible] fix that over the last, I'd say, six weeks. I don't remember seeing a catheter have that – physicians have that experience with the device with the new generation. So, the balloons leaking get some more CO_2, that's not really, that doesn't seem to be as big of an issue. And all of these are getting better. The balloons we're making the – balloons are stronger, and the fibers are more protected. So, I think everything is headed in the right direction. . . .
>
> **Analyst question**: OK. ***And the robustness issues seem to be relatively in the rear-view mirror. Is that right [for me to] think about it as it's going forward that these technical issues have been solved?***
>
> **Defendant Simpson**:

> I would say that that's – for [unintelligible] with 100%, but that's – 95%, those things are behind us. We're seeing – it's almost – I mean really rare compared to – I mean doc[tor]s will sometimes, you'd be surprised how aggressive the doc[tor]s will be forcing, pushing, jerking, twisting everything. And it's – and even though there's to be train[ing] against it, it still happen[s]. So I believe, though, that the robustness challenges that we found when we – in the initial launch – I think those are behind us.

64. Analysts were shocked by these disclosures. For example, a July 12, 2016 research report by BTIG stated the following:

> After the close, AVGR released preliminary Q2 top-line results of $4.7M, below the Street estimate of $5.7M. In addition, mgmt lowered full year guidance by ~25% at the midpoint. The revenue miss alone is not horrendous early in launch, ***but we found [management's] commentary alarming and plan to have near-term discussions with physician users***."
>
> ***Mgmt discussed product failures, and we see these as a meaningful problem.*** On the call, mgmt described issues with the catheter, including the light going out when reaching the narrowing of the artery and fiber issues. We had been under the impression these were entirely resolved months ago, ***but it seems while the company has made significant progress, issues still are more common than more-established competitive platforms***. Some device failure early on is expected, ***but repeated issues (especially of the imaging component) could really slow adoption. We plan calls with docs to see how often they are having issues now that it seems they are not entirely resolved***.

65. On July 13, 2016, ***Avinger's stock price fell $4.54 per share, or a staggering 39.7%***, from $11.43 at the close on July 12 to only $6.89 at the close on July 13, 2016, on unusually heavy trading volume.

66. On August 1, 2016, Avinger issued a press release announcing its final financial results for the second quarter of 2016. Referencing the company's product quality issues with the Pantheris, the press release quoted defendant Soinski as stating "We have improved the Pantheris imaging fiber connection to enhance device robustness" as part of an effort to "driv[e] Pantheris utilization and revenue growth in the second half of the year." The Company also announced that total revenue for the quarter ($4.7 million) was up sequentially only 3% compared to the immediately preceding quarter, even though the second quarter represented the first full quarter since the FDA had granted Pantheris 510(k) clearance on March 1, 2016. The Company further announced that its losses from operations for the second quarter of 2016 had risen to $12.3 million (from $9.1 million for the second quarter of 2015), and that the value of its cash and cash

equivalents on hand had declined from $43.1 million as of December 31, 2015 to only $22.4 million as of June 30, 2016.

67. On August 5, 2016, the Company issued its report for the 2d Quarter of 2016 on SEC Form 10-Q, which stated as follows:

> ***[W]e have in the past, and may in the future, become aware of performance issues with our products***. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. ***We have addressed certain of these concerns and plan to make additional product changes and improvements as a result of this feedback. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our reputation could suffer, which could lead to decreased sales of our products***. In the second quarter of 2016, our revenue was adversely impacted by these product performance issues. ***We also had to incur additional expenses to make product changes and improvements, including improvements to the Pantheris imaging fiber connection, and to replace products in accordance with our warranty policy. This additional expense, and any future expense that we may incur as a result of future product performance issues, will negatively impact our financial performance and results of operations***. If we are unable to improve the performance of our products to meet the concerns of the physicians our revenue may decline further or fail to increase.

68. Between the close of the market on July 29, 2016 (the last trading day before August 1) and the close of the market on August 5, 2016, the price of Avinger common stock fell a further $0.35, or more than 7%, from $4.94 to $4.59 per share.

69. On August 16, 2016, in order to raise desperately needed funds in light of the disappointing Pantheris launch (which was in turn the result of Pantheris' significant product quality and/or design problems), the Company announced that it had completed a secondary public offering of roughly 9.8 million shares. This secondary offering raised roughly an additional $31.7 million to keep Avinger afloat – but did so based on a secondary offering price of only $3.50 per share.

70. On the morning of January 6, 2017, Avinger issued a press release that pre-announced disappointing preliminary fourth quarter 2016 results. The Company announced that total revenue for the fourth quarter of 2016 was expected to be only $4.7 million, a decline of 11% sequentially from the third quarter of 2016 (and that revenue from "disposable devices", which

included the Pantheris, was expected to decline 5% over the same period, to only $3.7 million). The Company, while noting that its disposable revenue "continues to ramp more slowly than anticipated," tried to deflect attention from continuing problems with the existing Pantheris product by emphasizing that the Company was continuing to work on "improvements to our current version of Pantheris, which we plan to roll out in the coming months." The press release also noted that (even after taking into account the additional $31.7 million it had raised in its August 2016 secondary offering) the Company's cash and cash equivalents position as of December 31, 2016 was down to $36.1 million, and that its cash expenditures for the fourth of 2016 quarter totaled $11.0 million.

71. On January 6, 2017, Avinger's stock price fell $0.60 per share, or more than 15%, from $3.90 at the close on January 5 to close at only $3.30 on January 6, 2017.

72. On March 6, 2017, Avinger announced its fourth quarter and full year results for the fourth quarter of 2016. Among other things, the Company announced that its total revenue for the fourth quarter of 2016 had decreased 12% from the immediately preceding quarter, and confirmed that its revenue from disposable devices for the quarter had been only $3.7 (a 5% decline from the prior quarter). The Company also announced that its gross margin for the fourth quarter of 2016 had fallen to only 21% (down from 37% in the comparable quarter of 2015 and down sequentially from 30% in the third quarter of 2015), and that gross margins for the full year (2016) had fallen to only 15%, compared to 40% for 2015. The Company also confirmed that its loss from operations for the fourth quarter of 2016 was $12.0 million (down only $300,000 from the fourth quarter of 2015), and that its cash and cash equivalents position as of December 31, 2016 was $36.1 million.

73. After the close of the market, Avinger also held a conference call to discuss its fourth quarter and full year results for the fourth quarter of 2016. During the call, Avinger representatives discussed how product defect problems with the Pantheris remained and had still not been satisfactorily resolved – and effectively admitted that the Company's prior Pantheris testing regimen had been inadequate and would need to be substantially toughened to avoid the

kinds of product quality and design problems that had plagued the initial launch of the Pantheris. For example, as Defendant Soinski stated:

> I'd like to provide an update on our Pantheris product development efforts as we progress the next generation Pantheris . . . towards market launch. ***Our R&D teams have been working diligently to rollout a series of incremental improvements to our current version of Pantheris to improve the consistency and reliability of our currently marketed products*** while we are completing our verification and validation activities to ready the next generation of Pantheris for 510(k) submission midyear.
>
> Recall that the new Pantheris device is a true upgrade, which brings a host of additional improvements and important new features and benefits to the Pantheris franchise, including a more robust shaft for better pushability and improved handle designs, a redesigned single balloon system for apposition and occlusion as well as an improved nosecone and longer nosecone option. . . .
>
> We believe that the multiple improvements in this next generation device will allow us to broaden the applicable procedure market especially in tough to treat lesions and that it will have a direct and positive impact on increasing utilization rates in existing and new accounts.

In discussing Avinger's collapsing gross margins, Defendant Ferguson attributed much of the decline to the growth of the Company's manufacturing infrastructure associated with the commercial launch of Pantheris, but defendant Ferguson also admitted that "Gross margin for the fourth quarter was also negatively impacted by ***higher costs relating to product warranties and excess and obsolete inventories" –*** and that staggering decline in gross margins for the full year (2016) to only 15% was also "primarily attributable to the growth in manufacturing infrastructure in conjunction with the launch of Pantheris ***and higher costs related to product warranties and excess and obsolete inventories***."

74. Later during the same call, in discussing Avinger's plans to try to reverse its calamitous performance by launch certain "next generation" Pantheris products, Defendant Soinski also referenced the need for Avinger to toughen its prior testing standards to avoid a repeat of its disastrous launch of the its existing Pantheris product:

> As we look at [getting FDA approval for the next Pantheris] device, . . . we're giving ourselves [a?] little time there, because ***one of things that we've done – as I think we've talked about in past calls – is we have made our verification, validation [and] testing protocols tougher [and] a little more comprehensive because we want to make sure we're avoiding any potential quality issues prior to launch.*** So, we want to take the time to make sure that we've [got] these products right. We're very, very happy with the development programs that we're moving forward [with]. We've also pulled certain of the improvements that will be . . . in the next generation of Pantheris into our current device.

> So, we'll be rolling out this quarter and next quarter certain improvements relating to the inflation system, related to the nosecone on our current device. . . .

In addition, in response to an analyst question about the Company's declining margins and rising costs for product warranties, Defendant Ferguson stated:

> ***Yes, so in terms of gross margins, we've talked quite a bit about some of the reliability issues with Pantheris since it launched, and that has translated to a higher level of returns. And so that really is the main driver of higher than planned warranty expense.***
>
> We think we've gotten that under control pretty well ***but we would expect to continue to have it be higher than we really want it to be for the next couple of quarters until we can get some of these improvements in place***. And those will be both, some of the incremental improvements that will be coming out sooner and then the next generation of Pantheris, which is more of a wholesale upgrade of the device later in the year. So that's the main driver.

75. On March 7, 2017, ***Avinger's stock price fell a further $0.53 per share, or 20%***, from $2.65 at the close on March 6 to only $2.10 at the close on March 7, 2017.

76. On April 10, 2017, Avinger announced poor preliminary first quarter 2017 results, including total revenue of approximately $3.5 million, a decrease of 22% from the first quarter of 2016 and a sequentially decline of 25% from the immediately preceding fourth quarter of 2016, and revenue from disposable devices for the quarter of only $2.9 million, a 12% decrease compared to the first quarter of 2016 and down sequentially 22% from the immediately preceding quarter. The Company also announced that it had been conducting a review of potential strategic alternatives, including raising capital from strategic investors, partnerships for distribution of products outside the U.S., and a sale or merger of the Company. The Company was once again also forced to admit that it had continued to experience significant challenges with Pantheris' product reliability and related efforts to commercialize the Company's Lumivascular technology, and that, as a result, the Company would be making "adjustments" to its business" by, among other things, slashing its workforce by approximately 33%. In particular, the Company's April 10, 2017 press release stated:

> The Company . . . announced that it has been conducting a review of various strategic alternatives focused on maximizing shareholder value. Potential strategic alternatives being explored and evaluated as part of this review include, but are not limited to, raising capital from strategic investors, partnerships for distribution of products outside the U.S., and a sale or merger of the Company.

> "Avinger has achieved a great deal in the last year by bringing Pantheris OCT-guided atherectomy to market, increasing our installed base of Lumivascular accounts and presenting compelling two-year data from our VISION study. ***However, we have also encountered challenges with product reliability and the broad commercialization of our Lumivascular technology***. Consequently, we have decided to make adjustments in our business as we prepare for the launch of our next generation Pantheris and Below-the-Knee products in late 2017 and early 2018," said Jeff Soinski, Avinger's president and CEO.
>
> * * *
>
> **Organizational Realignment**
>
> The Company is reducing its workforce by approximately 33% compared to year-end 2016, to a total of 131 full-time equivalent employees, under a plan expected to be substantially completed this week. The plan is designed to focus the Company's commercial efforts on driving catheter utilization in its strongest markets, around its most productive sales professionals. The Company's field sales personnel will be reduced to 32 down from 60 people as of December 31, 2016.

77. Analysts again were shocked. For example, as an April 11, 2017 Stephens analyst report stated:

> **A Disappointing Pre-Announcement**. Following the market's close on Monday, April 10, AVGR pre-announced 1Q17 revenue of $3.5 million, approximately $1.3 million below our former $0.1 million below consensus quarterly revenue estimate of $4.8 million. Specifically, AVGR expects 1Q17 disposable device revenue of $2.9 million (Stephens former estimate of $3.8 million), implying a (12.0%) annual decline. Additionally, the Company sold a total of 5 Lightbox unit (Stephens former estimate of 15 units) during the quarter, bringing the installed base to 161 accounts. As a result, capital revenue declined 50.0% year-over-year to $0.6 million (Stephens former estimate of $1.0 million). AVGR exited the 1Q17 operating period with $23.0 million in cash and cash equivalents, implying a cash burn of $13.1 million during the quarter.

On April 11, 2017, the last day of the Class Period, Avinger's stock price fell a further $1.00 per share from $1.60 per share at the close on April 10, 2016 to close at only $0.60 per share at the close on April 11, 2017, on unusually heavy trading volume. On May 4, 2017, the Company announced its results for the first quarter of 2017, which confirmed that its total quarterly revenue would be only $3.5 million – a 23% decline from the first quarter of 2016 and a 25% decline from the fourth quarter of 2016.

78. In the following weeks and months, the price of Avinger's common stock has only continued to fall. On November 20, 2017 (the date immediately preceding the filing of the Consolidated Complaint), Avinger shares closed at $0.23 per share – reflecting a staggering a decline of $12.77 per share, ***and more than a 98% decline,*** from its IPO price of $13.00 per share.

LOSS CAUSATION

79. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions and engaged in a scheme to deceive the market. This course of wrongful conduct operated as a fraud or deceit on the Class and caused the price of Insulet common stock to be artificially inflated. But for Defendants' misrepresentations and omissions, Plaintiffs and the other members of the Class would not have purchased Insulet common stock, or would not have purchased such shares at artificially inflated prices.

80. The timing and magnitude of Avinger's stock price declines (as discussed above) negates any inference that the losses suffered by Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to defendants' fraudulent conduct. The economic loss, *i.e.* damages, suffered by Plaintiffs and other members of the Class, was a direct result of defendants' scheme and misrepresentations, which artificially inflated the price of Avinger common stock and the subsequent decline in the value of Avinger common stock as the true state of the Company's business, products, and operations was gradually disclosed, correcting the misrepresentations and/or economic impact thereof.

81. Nothing herein is intended to state or imply that any affirmative showing of loss causation is an element of Plaintiff's or the Class's burden of proof with respect to establishing Defendants' liability under the claims asserted herein under the Securities Act.

PRESUMPTION OF RELIANCE

82. At all relevant times, the market for Avinger's common stock was an efficient market for the following reasons, among others:

A. Avinger common stock met the requirements for listing, and was listed, and actively traded on NASDAQ, a highly efficient and automated market;

B. As a regulated issuer, Avinger filed periodic public reports with the SEC and NASDAQ;

C. Avinger regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press

releases on the national circuits of major newswire services, and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

E. Avinger was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace; and

F. There was a cause and effect relationship between unexpected corporate events or financial releases and movements in Avinger's stock price.

83. As a result of the foregoing, the market for Avinger common stock promptly digested current information regarding Avinger from all publicly available sources and reflected such information in the price of Avinger common stock. Under these circumstances, all purchasers of Avinger common stock during the Class Period suffered similar injury through their purchase of Avinger common stock at artificially inflated prices and the presumption of reliance applies.

84. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding problems with its Pantheris product that Defendants were obligated to disclose, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Company's Pantheris business, as set forth above, that requirement is satisfied here.

CLASS ACTION ALLEGATIONS

85. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons and/or entities who purchased or acquired the Company's common stock during the Class Period, including all persons and entities that

purchased or otherwise acquired shares of Avinger common stock pursuant and/or traceable to the Offering Documents, and who were damaged thereby (collectively, the "Class"). Excluded from the Class are each of the Defendants, their respective successors, assigns, parents and subsidiaries; the past and current executive officers and directors of Avinger and the Underwriter Defendants; the legal representatives, heirs, successors, or assigns of any excluded person; and any entity in which any of the above excluded persons have or had a majority ownership interest.

86. The members of the Class are so numerous that joinder of all members is impracticable. For example, the Company sold approximately five million shares in the IPO, and thereafter, Avinger's common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Avinger or its transfer agent, and may be notified of the pendency of this action by mail using forms of notice similar to that customarily used in securities class actions.

87. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law, as alleged herein.

88. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

89. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' acts constituted violations of the Securities Act and/or the Securities Exchange Act and Rule 10b-5 promulgated thereunder;

(b) whether Defendants' statements (including those made in the Offering Documents) made to the investing public misrepresented or omitted material facts required to be disclosed concerning the Company's business, products, operations, or prospects;

(c) whether the price of Avinger's common stock was artificially inflated during the Class Period;

(d) whether Avinger and the Individual Defendants knew or recklessly disregarded that their Class Period statements were materially false or misleading; and

(e) the extent to which the members of the Class have sustained damages, and the proper measure of damages.

90. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CLAIM
Violation of Section 11 of the Securities Act
(Against All Defendants)

91. Plaintiffs repeat and reallege each and every allegation contained above, except any allegation of fraud, recklessness or intentional misconduct. Plaintiffs specifically disclaim any allegations that are based upon fraud, recklessness or intentional misconduct.

92. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of Plaintiffs and all other members of the Class, who purchased or otherwise acquired Avinger common stock pursuant or traceable to the Offering Documents, against all Defendants.

93. The IPO Registration Statement was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and otherwise omitted to state material facts required to be stated therein.

94. This claim is not based on and does not sound in fraud. For purposes of asserting this claim under the Securities Act, Plaintiffs do not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

95. Avinger was the issuer and registrant for the IPO. The Defendants named herein were responsible, either directly as a matter of law, for the contents and dissemination of the IPO Registration Statement.

96. As issuer of the shares, Avinger is strictly liable to Plaintiffs and the Class for the misstatements and omissions.

97. In addition, all Defendants other than Avinger are also strictly liability to Plaintiffs and the Class for the misstatements and omissions. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the IPO Registration Statement were true and without omissions of any material facts and were not misleading.

98. By reason of the inaccuracies and omissions contained in the Registration Statement and their role in its preparation, dissemination and/or signing, and/or the other misconduct alleged herein, each Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

99. At the time they purchased or acquired their Avinger shares, Plaintiffs and the other members of the Class, who acquired Avinger shares pursuant and/or traceable to the IPO Registration Statement, did not know, nor in the exercise of reasonable diligence could have known, of the untrue statements of material fact or omissions of material facts in the Offering Documents. .

100. Plaintiffs and the Class have sustained damages under Section 11(e) of the Securities Act, as the value of the shares of Avinger common stock declined following the IPO.

SECOND CLAIM
Violation of Section 15 of the Securities Act
(Against the Individual Defendants)

101. Plaintiffs repeat and reallege each and every allegation contained above, except any allegation of fraud, recklessness or intentional misconduct. Plaintiffs specifically disclaim any allegations that are based upon fraud, recklessness or intentional misconduct.

102. This count is asserted on behalf of Plaintiffs and all other members of the Class, who purchased or otherwise acquired Avinger common stock pursuant or traceable to the Offering Documents, against the Individual Defendants, and is based upon Section 15 of the Securities Act.

103. This claim is not based on and does not sound in fraud. For purposes of asserting this claim under the Securities Act, Plaintiffs do not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

104. The Individual Defendants, by virtue of their offices, directorship and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Avinger within the meaning of Section 15 of the Securities Act. The Individual Defendants had the power and influence, and exercised the same, to cause Avinger to engage in the acts described herein.

105. The Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiffs and the Class.

106. By virtue of the conduct alleged herein, the Individual Defendants are liable to Plaintiffs and the Class for damages they have suffered.

THIRD CLAIM
Violation of Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 Promulgated Thereunder
(Against Defendants Avinger and the Individual Defendants)

107. Plaintiffs repeat and reallege each and every allegation contained above as though set forth in full herein.

108. This count is asserted on behalf of Plaintiffs and all other members of the Class against the Individual Defendants, and is based upon Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder.

109. During the Class Period, Avinger and the Individual Defendants disseminated or approved the materially false and misleading statements specified above, which they knew, or were deliberately reckless in not knowing, were misleading. These statements were false and misleading because they contained misrepresentations and failed to disclose material facts

necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

110. Avinger and the Individual Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact/and or omitted to state material facts necessary to make the statements made not misleading; and (3) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

111. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiffs and the Class would not have purchased the Company's common stock at the prices they paid – or at all – if they had been aware that the market prices had been artificially and falsely inflated by Avinger's and the Individual Defendants' misleading statements.

112. As a direct and proximate result of Avinger's and the Individual Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

FOURTH CLAIM
Violation of Section 20(a) of the Securities Exchange Act
(Against the Individual Defendants)

113. Plaintiffs repeat and reallege each and every allegation contained above as though set forth in full herein.

114. The Individual Defendants acted as controlling persons of the Company within the meaning of Section 20(a) of the Securities Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the Company's statements filed with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements alleged to be false and misleading herein.

115. The Individual Defendants, moreover, were provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings, and other statements alleged to be false and misleading herein. The Individual Defendants were provided with, or had unlimited access to, such documents and statements prior to, and/or shortly after these statements were issued, and therefore, had the ability to prevent the issuance of the statements and/or cause the statements to be corrected. Additionally, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and had the power to control or influence the particular transactions giving rise to the securities violations.

116. The Individual Defendants all had ultimate authority over the Company's statements, including controlling the content of such statements and whether and how to communicate such statements to the public.

117. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Securities Exchange Act.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: March 19, 2018

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Additional Counsel for Plaintiffs

ATTESTATION

I, John T. Jasnoch, am the ECF User whose ID and password are being used to file this Amended Consolidated Class Action Complaint. In compliance with Civil Local Rule 5-1(i)(3), I hereby attest that William C. Fredericks has concurred in this filing.

/s/ John T. Jasnoch
John T. Jasnoch (CA 281605)

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury under the laws of the United States of America that, on March 19, 2018, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses for all counsel of record (which includes counsel for all parties) in this action. I further certify in accord with F.R.C.P. 15(a)(2) that Defendants have given their written consent to Plaintiffs' filing of an amended complaint.

/s/ John T. Jasnoch
John T. Jasnoch (CA 281605)